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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/627,531	Applicant(s) BERRY ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-21,23-27,29-31,33-41 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-21,23-27,29-31,33-41 and 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/05/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and IDS filed 1/17/06. Claims 17-21, 23-27, 29-31, 33-41 and 49-53 are pending.

Upon further consideration of the claims amended and filed 01/07/2005, it is noted that the claims as filed 01/07/2005 and currently pending recite analogs and derivatives of the peptides, nucleotides, hormone, virus and antibody. The statement about the analogs and derivatives is found in the specification at paragraph [0039] without description of what the analogs and derivatives of the peptides, nucleotides, hormone, virus and antibody are. Thus, a written description is lacking for analogs and derivatives. The rejection below thus follows.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 17-21, 23-31, 33-41 and 49-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicants were in possession of the claimed invention. There is no description in the specification for analogs and derivatives of the peptides, nucleotides, hormone, virus and antibody.

Claims directed to analogs and derivatives of the peptides, nucleotides, hormone, virus and antibody are neither described nor exemplified. The specification does not inform the public of the limits of the monopoly asserted. The expression provided in the specification on page 10 paragraph [0039] represents only an invitation to experiment regarding the possible analogs and derivatives of the peptides, nucleotides, hormone, virus and antibody claimed in the instant application.

4. Claims 17-21, 23-31, 33-41, 49-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims appear to be referring to suspensions or that beneficial agents are suspended in the vehicle. A suspension is not a single phase. However, the claims direct the compositions to be single phase and it is not clear how a suspension could be a single phase. Clarification is respectfully requested.

The recitation of analogs and derivatives in the claims is unclear as to what the analogs and derivatives are referring to. For examination purposes, analogs and derivatives are taken to mean analogs and derivatives of peptides, nucleotides, hormone and virus. Clarification and correction are respectfully requested.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claims 17-21, 23-27, 29-31, 33-41 and 49-53 under 35 U.S.C. 103(a) as being unpatentable over Daher et al. US 4,376,118) in view of Bogdanský et al. (US 5,284,655) is withdrawn in view of applicants' partially persuasive argument.

7. Claims 17-21, 23-27, 30, 31, 33-36, 38, 40, 41 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) in view of Gyory (US 5,668,170)

Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) discloses compositions comprising testosterone, lauryl lactate, lactic acid, glycerol monolaurate, DEA and EVA (Table 1). Testosterone is a hormone, meeting the hormone limitation of the beneficial agent. DEA and EVA meet the limitation of polymer in claims 17, 16 and 33. Lee's composition enhances the permeation of active agents through the skin and is topically administered.

Gyory discloses compositions that are delivered through the body surface in the presence of electrotransport enhancers (abstract); lauryl lactate and polysorbate and PEG-4 dilaurate are listed as electrotransport enhancers (Table 1 and column 14, lines 53,63 and 64); testosterone, tetracaine, peptides and proteins are few of the beneficial agents that are deliverable with the electrotransport delivery device of Gyory (column 7, lines 18, 20 and 25-52).

Polyvinylpyrrolidone is preferred polymer that is blended with the beneficial agent in any ratio

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(column 10, lines 32-35 and 56). Testosterone is a hormone that meets the limitation of the claimed beneficial agent.

The composition of Lee enhances the transport of beneficial agents through the skin. The composition of Gyory enhances the transport of beneficial agents through the skin.

Lee discloses composition containing testosterone, lauryl lactate, lactic acid, glycerol monolaurate, DEA and EVA. The composition of Lee does not contain surfactant. However, Gyory discloses a delivery vehicle that contains polymer, lauryl lactate and surfactant such as polysorbate. Regarding the selection of solvent and surfactant and polymer for a formulation that would exhibit viscosity that is capable of suspending the beneficial agent, it is noted that the skilled artisan or the person of ordinary skill is technically able, using the general teaching of Lee and/or Gyory, to formulate a composition that would be able to suspend the beneficial agent. Regarding claim 25, 26 and 31, stability of the formulation for the designated time is a property/characteristic of the formulation and a formulation/product cannot have mutually exclusive properties. Adaptation of a formulation for use in an implantable device as in claim 27 is an intended use/route of the composition, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The limitation of claims 50-53 is met by the presence of glycerol monolaurate in Lee and polysorbate surfactant in Gyory. Regarding the recited amounts active agent, Gyory discloses that the active agent is blended with the polymer in any ratio and Lee discloses 10% testosterone. However, there is also no demonstration in applicants' specification showing that the amounts recited for the beneficial

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agents provide unusual and unexpected results. It is within the purview of the skilled artisan or the ordinary skilled practitioner to use amounts of solvent and polymer adequate for the formulation. Regarding claims 40 and 41, it is within the purview of the ordinary or skilled artisan to determine duration of treatment or effective management of the condition being treated. The skilled artisan or the ordinary person in the art is able to determine how much solvent, surfactant and polymer to use.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Lee to formulate a testosterone for enhanced topical delivery. One having ordinary skill in the art would have been motivated to combine the composition of Lee and Gyory to make a third formulation for the same purpose. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

8. Claims 17, 29, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,882,676 provided by applicants on Form PTO 1449) in view of Gyory (US 5,668,170) and further in view of Benson et al. (US 4,078,060).

The combined teaching of Lee and Gyory is described above. However, the combined teaching of Lee and Gyory does not include antioxidants. But Benson discloses that testosterone can be administered parenterally, by depot injection or implantation (column 3, lines 18-54; column 4, lines 53 and 54; column 5, lines 32, 46; column 10, lines 42 and 43; Table 1); the

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composition can also contains antioxidant (column 6, lines 3-10). Thus Benson shows that antioxidant can be included with testosterone. Regarding implantation and parenteral administration, it is known in the art that testosterone can be administered parenterally or by implantation as disclosed by Benson.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Lee and Gyory and add antioxidant as disclosed by Benson to protect the testosterone composition form oxidizing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

